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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,863	03/31/2004	Edward Vaquero	P03166	5586
23702 7590 01/21/2010 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701				
EXAMINER				
LANG, AMY T				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
01/21/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/813,863

Applicant(s)

VAQUERO, EDWARD

Examiner

AMY T. LANG

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 6-13 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 26-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 22-25 is/are allowed.
- 6) ☒ Claim(s) 1, 4 and 6-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. In view of appeal brief filed on 09/30/2009, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

Claim Rejections – 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

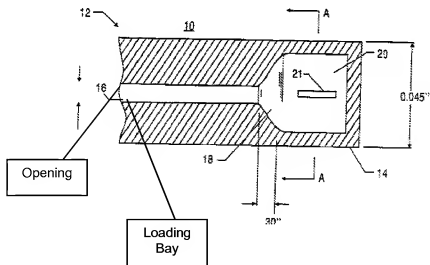
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 6, and 8-11** are rejected under 35 U.S.C. 102(b) as being anticipated by Baudino (US 6,139,539) in view of the evidence given by Sacharoff et al. (US 2009/0281620 A1).

With regard to **claim 1**, Baudino discloses a device for ejecting liquid to a treatment site (see entire document). As shown in Figure 1, the device comprises an injector body (10) having a lumen that expands from a smaller diameter portion (16) to a larger diameter portion (20) at the distal end (column 3, lines 16-18, 35-36). The increase in diameter advantageously slows liquid moving within the device before it is ejected out through distal tip 21 to prevent tissue trauma (column 3, line 37 through column 4, line 2).

Baudino further teaches wherein the liquid is introduced by coupling the proximal end (12) to a fluid supply device (column 2, line 55 through column 3, line 15). Therefore, the proximal end comprises a hole or aperture to which the fluid supply device is connected. It is this proximal hole or aperture that overlaps the claimed opening. The proximal portion of the lumen immediately adjacent to this hole forms a loading bay where an implant can be placed.



Since the diameter of the lumen increases at the distal end (20), the inner diameter of the lumen at a location immediately adjacent and distal to the loading bay is less than an inner diameter of the lumen at the open tip (noting that the open tip is formed at slit 21).

Baudino further teaches wherein the lumen is configured for transportation of an IOL implant. The catheter is designed to transport liquid so that the proper medium is present to move the IOL (column 1, lines 11-12). Additionally, Baudino discloses the smallest size of the lumen as 0.015 inches which is configured for placement of an IOL. If Applicant were to argue such, attention is drawn to Sacharoff which provides evidence that IOLs are micro-sized ([0026]; [0027]).

With regard to **claim 6**, the outer diameter of the device of Baudino is substantially constant (Figure 1).

With regard to **claims 8-11**, as shown in Figure 1 of Baudino, the inner diameter of the lumen increases with a gradual step.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 7, 12, and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino (US 6,139,539).

Baudino, as discussed above, discloses a catheter that is configured to deliver an IOL implant. Although Baudino does not specifically disclose the outer diameter of the device as increasing in size from the proximal end to the distal end, such is deemed a matter of design choice. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art for the outer diameter to follow the inner lumen because Applicant has not disclosed that an increased outer diameter of the distal end of the device compared to the proximal end provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a constant outer diameter because such would still allow the inner lumen to increase in diameter.

7. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino (US 6,139,539) in view of Callahan et al. (US 2005/0033308 A1).

Baudino, as discussed above, discloses a catheter that is configured to deliver an IOL implant. The proximal end of the device is attached to a syringe assembly to deliver the fluid and implant (column 3, lines 13-15). However, Baudino does not specifically disclose a plunger configured to slide within the lumen of the device.

Callahan discloses a device for delivering an IOL implant (see entire document). As shown in Figures 13 and 14, the device comprises a syringe assembly to drive the liquid, and therefore the IOL, towards the distal tip ([0043]). Callahan teaches this syringe assembly comprises a plunger (72) to drive the liquid forward ([0069]). As shown in Figure 13, the plunger (72) is inserted directly into the inner lumen of the device for direct force against the liquid.

Since Baudino also discloses a syringe assembly and Callahan teaches that such can comprise a plunger, it would have been obvious at the time of the invention for the device of Baudino to further comprise a plunger. Additionally, it would have been obvious at the time of the invention for the plunger to be inserted directly into the lumen of the Baudino device. This would produce a direct force against the liquid to adequately move the liquid down the lumen. By inserting the plunger within the lumen, the plunger is configured to engage the IOL and push the IOL toward the distal tip. The functional limitation "configured to" is not given full patentable weight. As long as the prior art meets the structural requirements and is capable of performing the functions, the prior art meets the limitations. In the instant case, the device of Baudino in view of

Callahan meets all the structural requirements and is capable of performing the intended function. Additionally, the term "engaging" does refer to direct contact of the plunger with the IOI, but can be merely pushing liquid in the lumen that then alters the location of the IOL.

Allowable Subject Matter

8. Claims 3 and 23-25 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

01/15/2009

/Amy T Lang/

Examiner, Art Unit 3731

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Anhtuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

01/18/2010